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REED SMITH, LLP
ATTN: PATENT RECORDS DEPARTMENT
599 LEXINGTON AVENUE, 29TH FLOOR
NEW YORK, NY 10022-7650

EXAMINER	
DWIVEDI, MAHESH H	

ART UNIT	PAPER NUMBER
2168	

MAIL DATE	DELIVERY MODE
09/29/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/517,289	DOERING, AXEL
	Examiner	Art Unit
	MAHESH H. DWIVEDI	2168

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _3_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _24 June 2009_.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) _7-12_ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) _7-12_ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _07 December 2004_ is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Remarks

1. Receipt of Applicant's Amendment, filed on 06/24/2009, is acknowledged.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 7-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Sinclair et al.** (U.S. PGPUB 2002/0052551) and in view of **Huang et al.** (U.S. Patent 6,293,674).

5. Regarding claim 7, **Sinclair** teaches a method comprising:

A) determining deviations from the contextual information (a) of a stored comparison image and/or (b) of a standard image created by evaluating a plurality of comparison images of a similar pathology (Paragraphs 19, 166-167, 231-232, 234, and 252-267); and/or

B) carrying out a similarity analysis from the contextual information (a) of a stored comparison image, and/or (b) of a standard image created by evaluating a plurality of comparison images of a similar pathology (Paragraphs 19, 72, 166-167, 231-232, 234, and 252-267); and

C) creating new images that is stored for comparison at a later time (Paragraphs 44 and 72);

D) wherein the stored comparison image is chosen from a database of images (Paragraphs 44 and 131);

E) the database of images comprising images of the same eye (Paragraphs 44 and 131);

F) wherein the contextual information is drawn from the settings of the fundus camera, manual annotations associated with the recorded fundus images, patient-specific information, and image contents (Paragraphs 119, 131, 134, 140, 228, and 238).

The examiner notes that **Sinclair** teaches **"determining deviations from the contextual information (a) of a stored comparison image and/or (b) of a standard image created by evaluating a plurality of comparison images of a similar pathology"** as "Another significant element of this invention is one or more retinal grading algorithms that automatically evaluate the digital retinal images obtained by the screening subsystems for particular retinopathies. Generally, the RGAs operate in a lesion-based fashion, first identifying ophthalmologically significant retinal lesions or features by use of image processing methods, and second evaluating and grading the retinopathy in view of the identified lesions by use of artificial intelligence/cognitive decision capabilities" (Paragraph 19), "The RGAs are based on detecting and identifying "lesions" in fundus images. Therefore, each image (field of view) is evaluated to detect the number and type of lesions, and the cumulative lesion information for all acquired images is processed to arrive at a final retinopathy grade level for each eye. This processing may be by an expert system, perhaps rule-based, that simulates the considerations of an ophthalmologist when presented with similar cumulative lesion information" (Paragraph 231), and "In somewhat more detail, the following lists DR lesions that are preferably detected and identified by all RGA algorithms. Sophisticated RGA algorithms for DR detect additionally the advantageous lesions. DR Lesions and Characteristics Preferably Identified…Fovea (or approximate foveal location)… Epi-retinal (or epi-papillary) neovascularization--size and distance to optic nerve head or fovea" (Paragraphs 252-265). The examiner further notes that **Sinclair** teaches **"carrying out a similarity analysis from the contextual information (a) of a stored comparison image, and/or (b) of a standard image created by evaluating a plurality of comparison images of a similar pathology"** as "Also, in preferred embodiments where prior retinal images are available and may be compared to a

current retinal image, the time progression or regression of lesions may be identified. Then, detailed lesion information and lesion history may be taken into account in adjusting retinal image grading. For example, if a current image received a grade of level 2, but it contained lesions in critical anatomic regions as near the optic nerve head, or the fovea, or so forth, or contained rapidly growing or multiplying lesions, it may be promoted to grade level 3. Conversely, if a current image received a grade of level 3, but it contained regressing lesions in locations posing no threat of imminent visual impairment, it may be demoted to grade level 2 (or 2+) (Generally, grade level 3 signifies specialist consultation is recommended, while grade level 2 signifies that routine follow-up screening is recommended.)" (Paragraph 72), "The RGAs are based on detecting and identifying "lesions" in fundus images. Therefore, each image (field of view) is evaluated to detect the number and type of lesions, and the cumulative lesion information for all acquired images is processed to arrive at a final retinopathy grade level for each eye. This processing may be by an expert system, perhaps rule-based, that simulates the considerations of an ophthalmologist when presented with similar cumulative lesion information" (Paragraph 231), and "In somewhat more detail, the following lists DR lesions that are preferably detected and identified by all RGA algorithms. Sophisticated RGA algorithms for DR detect additionally the advantageous lesions. DR Lesions and Characteristics Preferably Identified…Fovea (or approximate foveal location)… Epi-retinal (or epi-papillary) neovascularization--size and distance to optic nerve head or fovea" (Paragraphs 252-265). The examiner further notes that **Sinclair** teaches **"creating new images that is stored for comparison at a later time"** as "identify, and characterize in the prior retinal images lesions from the pre-determined set lesions type, comparing the lesions detected in the image taken at the selected time with the lesions detected in the prior image to detect changes in the lesions, and performing a decision process that assigns a grade to the retinal image taken at the selected time in dependence on the identities and characteristics of the lesions detected in that image, and in dependence on the changes in the lesions detected in the comparing step" (Paragraph 44) and "Also, in preferred embodiments where prior retinal images are available and may be compared to a current retinal

image, the time progression or regression of lesions may be identified. Then, detailed lesion information and lesion history may be taken into account in adjusting retinal image grading. For example, if a current image received a grade of level 2, but it contained lesions in critical anatomic regions as near the optic nerve head, or the fovea, or so forth, or contained rapidly growing or multiplying lesions, it may be promoted to grade level 3. Conversely, if a current image received a grade of level 3, but it contained regressing lesions in locations posing no threat of imminent visual impairment, it may be demoted to grade level 2 (or 2+) (Generally, grade level 3 signifies specialist consultation is recommended, while grade level 2 signifies that routine follow-up screening is recommended.)" (Paragraph 72). The examiner further notes that **Sinclair** teaches **"wherein the stored comparison image is chosen from a database of images"** as "identify, and characterize in the prior retinal images lesions from the pre-determined set lesions type, comparing the lesions detected in the image taken at the selected time with the lesions detected in the prior image to detect changes in the lesions, and performing a decision process that assigns a grade to the retinal image taken at the selected time in dependence on the identities and characteristics of the lesions detected in that image, and in dependence on the changes in the lesions detected in the comparing step" (Paragraph 44) and "The central database ("CDB") is an on-line (or otherwise efficiently accessible) storage repository of the data generated in an OSS system. The CDB stores patient oriented data such as original image data from patient screening examinations, results of RGA screening including images annotated or marked-up with lesion identification, associated patient identification, demographics, and screening/examination history, results of manual ophthalmologist grading process including any annotated images, referrals and reports. This database also stores system oriented data such as statistical data gathered from analysis of the patient data, results of the image quality assessment process, the `rules` to be used by the WFM for handling images, reports, and messages" (Paragraph 119), "Screening session identification (screening site identification, date, time, confirmation of patient data, race (affects image processing parameters), sex, photographer, camera utilized and type of images acquired)", (Paragraph 131). The examiner further notes that

Sinclair teaches **“the database of images comprising images of the same eye”** as “identify, and characterize in the prior retinal images lesions from the pre-determined set lesions type, comparing the lesions detected in the image taken at the selected time with the lesions detected in the prior image to detect changes in the lesions, and performing a decision process that assigns a grade to the retinal image taken at the selected time in dependence on the identities and characteristics of the lesions detected in that image, and in dependence on the changes in the lesions detected in the comparing step” (Paragraph 44) and “The central database ("CDB") is an on-line (or otherwise efficiently accessible) storage repository of the data generated in an OSS system. The CDB stores patient oriented data such as original image data from patient screening examinations, results of RGA screening including images annotated or marked-up with lesion identification, associated patient identification, demographics, and screening/examination history, results of manual ophthalmologist grading process including any annotated images, referrals and reports. This database also stores system oriented data such as statistical data gathered from analysis of the patient data, results of the image quality assessment process, the `rules` to be used by the WFM for handling images, reports, and messages” (Paragraph 119), “Screening session identification (screening site identification, date, time, confirmation of patient data, race (affects image processing parameters), sex, photographer, camera utilized and type of images acquired)”, (Paragraph 131). The examiner further notes that **Sinclair** teaches **“wherein the contextual information is drawn from the settings of the fundus camera, manual annotations associated with the recorded fundus images, patient-specific information, and image contents”** as “The central database ("CDB") is an on-line (or otherwise efficiently accessible) storage repository of the data generated in an OSS system. The CDB stores patient oriented data such as original image data from patient screening examinations, results of RGA screening including images annotated or marked-up with lesion identification, associated patient identification, demographics, and screening/examination history, results of manual ophthalmologist grading process including any annotated images, referrals and reports. This database also stores system oriented data such as statistical data gathered from

analysis of the patient data, results of the image quality assessment process, the `rules` to be used by the WFM for handling images, reports, and messages" (Paragraph 119), "Screening session identification (screening site identification, date, time, confirmation of patient data, race (affects image processing parameters), sex, photographer, camera utilized and type of images acquired)", (Paragraph 131), "Screening session identification (screening site identification, date, time, confirmation of patient data, race (affects image processing parameters), sex, photographer, camera utilized and type of images acquired)" (Paragraph 134), "Equipment available (cameras, other resources)" (Paragraph 140), "RGA results from complete evaluation of all fundus images are stored in the Central Database. Preferably, RGA results include evaluated image annotated or marked-up with indicia to identify, e.g., the position or the identity of detected lesions. In cases of doubt, the annotation may include indications of "definitely a lesion," or "possibly a lesion." Annotations can include highlighting, coloring, outlining, pointing with arrows or the equivalent, and other methods known in the art (such as text superimposed on the image). Color coding of lesion characteristics may be used to simplify interpreting the annotations. The annotated images are saved (using an appropriate naming convention) along with the original images in the CDB" (Paragraph 228), and "Finally, RGAs have been discovered to be dependent on camera properties, digital image pixel density, depth and the magnification, and so forth. This dependence is preferably factored into RGA processing, for example, by inverse transforming known effects from the image" (Paragraph 238).

Sinclair does not explicitly teach:

E) the database of images comprising images of other eyes.

Huang, however, teaches **"the database of images comprising images of other eyes"** as "Examples of such databases and apparatus are databases stored on disk storage that are accessible from a computer such as, for example, a personal computer. Still further, in accordance with these other embodiments of the present invention, the measures are compared with measures taken from normal eyes to diagnose eye disease, and the measures may also be compared with measures taken

from the same patients (made over a period of time)" (Column 5, lines 66-67-Column 6, lines 1-6).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the cited references because teaching **Huang's** would have allowed **Sinclair's** to provide a method to enhance the monitoring of eye diseas, as noted by **Huang** (Column 6, lines 6-7).

Regarding claim 8, **Sinclair** further teaches a method comprising:
A) wherein the evaluation is carried out by averaging extracted features (Paragraphs 305-344).

The examiner notes that **Sinclair** teaches **"wherein the evaluation is carried out by averaging extracted features"** as "The following lists exemplary and non-limiting statistical information which may be obtained and accumulated in an OSS implementation. The following statistical parameters may be accumulated to aid in quality control and oversight of an OSS. Exemplary Quality Control Statistics…Percent of eyes with more advanced lesions noted in each field (1, 2, 3, 4 or 5) without equivalent lesions noted in other fields. Percent of patients who complied with recommendation for screening and follow-up screening; time interval between receipt of recommendation/referral by patient and actual follow-up screening. Sensitivity & specificity of the grading algorithm as compared with the gold standard of grading performed by the retinal specialist--for each eye (variance with age, pupil size, necessity for dilation, presence of cataract)" (Paragraphs 305-344). The examiner further notes that the various statistical analysis of the fundus properties of patients is analogous to an averaging function.

Regarding claim 9, **Sinclair** further teaches a method comprising:
A) wherein deviations are determined and/or the similarity analysis is carried out on the basis of a gray-value analysis and/or an analysis of color histograms and/or a structure analysis (Paragraphs 19, 166-167, 231-232, 234, and 252-267).

The examiner notes that **Sinclair** teaches **“wherein deviations are determined and/or the similarity analysis is carried out on the basis of a gray-value analysis and/or an analysis of color histograms and/or a structure analysis”** as “Another significant element of this invention is one or more retinal grading algorithms that automatically evaluate the digital retinal images obtained by the screening subsystems for particular retinopathies. Generally, the RGAs operate in a lesion-based fashion, first identifying ophthalmologically significant retinal lesions or features by use of image processing methods, and second evaluating and grading the retinopathy in view of the identified lesions by use of artificial intelligence/cognitive decision capabilities” (Paragraph 19), “The RGAs are based on detecting and identifying "lesions" in fundus images. Therefore, each image (field of view) is evaluated to detect the number and type of lesions, and the cumulative lesion information for all acquired images is processed to arrive at a final retinopathy grade level for each eye. This processing may be by an expert system, perhaps rule-based, that simulates the considerations of an ophthalmologist when presented with similar cumulative lesion information” (Paragraph 231), and “In somewhat more detail, the following lists DR lesions that are preferably detected and identified by all RGA algorithms. Sophisticated RGA algorithms for DR detect additionally the advantageous lesions. DR Lesions and Characteristics Preferably Identified…Fovea (or approximate foveal location)… Epi-retinal (or epi-papillary) neovascularization--size and distance to optic nerve head or fovea” (Paragraphs 252-265). The examiner further notes that paragraph 11 of the specification of the instant application defines a structural analysis of as “classification and quantification of structures at the ocular fundus (e.g., papilla, fovea)”.

Regarding claim 10, **Sinclair** further teaches a method comprising:

A) wherein an extraction of vascular tree parameters is carried out (Paragraphs 268-272).

The examiner notes that **Sinclair** teaches **“wherein deviations are determined and/or the similarity analysis is carried out on the basis of a gray-value analysis and/or an analysis of color histograms and/or a structure analysis”** as “Second,

diameter and tortuosity measurements for major vessel abnormalities including: Major artery tortuosity--deviations of 1.sup.st, 2.sup.nd, and 3.sup.rd order arteries from a straight line (point-to-point); also requires determination of whether the deviations are caused by branchings or by deviations between branchings; in other words, if a vessel branches unequally (daughter vessels are unequal in caliber), this causes a deviation of the large parent vessel into the larger of the two daughter vessels, Major vein tortuosity--deviations of 1.sup.st, 2.sup.nd, and 3.sup.rd order veins from a straight line (point-to-point) and whether deviations are caused by branchings or by deviations in between branchings, Major artery diameter (and variation in diameter) versus distance along vessel starting at the optic nerve head--for 1.sup.st and 2.sup.nd order vessels; second order vessels are defined as either two daughter vessels after an equal branching (branching in which both daughter vessels are of same caliber) or the smaller caliber vessel of the daughter vessels in an unequal branching, Major vein diameter (and variation in diameter) versus distance along vessel--for 1.sup.st and 2.sup.nd order vessels." (Paragraphs 268-272).

Regarding claim 11, **Sinclair** teaches a system comprising:

A) a fundus camera for recording the ocular fundus (Paragraphs 88-89, and 184);

B) an image storage for storing recorded fundus images (Paragraphs 24, 119-121, 166, and 228); and

C) means for evaluating the recorded fundus images of a similar pathology comprising means for analyzing the images according to the same or similar contextual information, for gray-value analysis and/or means for preparing color histograms and/or means for structure analysis (Paragraphs 19, 166-167, 231-232, 234, and 252-267);

D) a comparison unit connected to the image storage (Paragraphs 44 and 72); and

E) wherein the comparison unit can compare images to at least one image from a database of images (Paragraphs 44 & 131);

F) the database of images comprising images of the same eye;

G) wherein the contextual information is drawn from the settings of the fundus camera, manual annotations associated with the recorded fundus images, patient-specific information, and image contents (Paragraphs 119, 131, 134, 140, 228, and 238); and
H) wherein the comparison unit compares images recording in the image storage and creates new images of a similar pathology (Paragraphs 44 and 72).

The examiner notes that **Sinclair** teaches **"a fundus camera for recording the ocular fundus"** as "For image capture and acquisition, preferably a non-mydriatic retinal camera is used to acquire retinal images in order to avoid the patient inconvenience of pupil dilation (mydriasis)" (Paragraph 88), "The present invention may use a wide range of non-mydriatic cameras, including commercially-available cameras from, e.g., Canon, Nikon, and so forth, and also including specially designed and built cameras. From whatever source, preferred cameras have should have optics capable of acquiring up to 45.degree. retinal fields through pupils down to 2.0 mm in diameter with adequate image contrast and resolution" (Paragraph 89), and "retinal (fundus) camera with CCD sensors" (Paragraph 184). The examiner further notes that **Sinclair** teaches **"an image storage for storing recorded fundus images"** as "The central database ("CDB") is an on-line (or otherwise efficiently accessible) storage repository of the data generated in an OSS system. The CDB stores patient oriented data such as original image data from patient screening examinations, results of RGA screening including images annotated or marked-up with lesion identification, associated patient identification, demographics, and screening/examination history, results of manual ophthalmologist grading process including any annotated images, referrals and reports" (Paragraph 119) and "The CDB has several uses in an OSS, and its centralized image (also possible with distributed database architectures) provides several advantages. Its principal use is to provide physicians, specialists, ophthalmologists, and other users with access to current images as well as the results of any prior studies, regardless of where acquired. This historical record permits an objective and quantitative evaluation, either by automatic algorithmic processes or by manual physician examination, of the status and progression of the ocular disease in individual patients" (Paragraph 121). The examiner further notes that **Sinclair** teaches **"means for evaluating the recorded**

fundus images of a similar pathology comprising means for analyzing the images according to the same or similar contextual information, for gray-value analysis and/or means for preparing color histograms and/or means for structure analysis" as "Another significant element of this invention is one or more retinal grading algorithms that automatically evaluate the digital retinal images obtained by the screening subsystems for particular retinopathies. Generally, the RGAs operate in a lesion-based fashion, first identifying ophthalmologically significant retinal lesions or features by use of image processing methods, and second evaluating and grading the retinopathy in view of the identified lesions by use of artificial intelligence/cognitive decision capabilities" (Paragraph 19), "The RGAs are based on detecting and identifying "lesions" in fundus images. Therefore, each image (field of view) is evaluated to detect the number and type of lesions, and the cumulative lesion information for all acquired images is processed to arrive at a final retinopathy grade level for each eye. This processing may be by an expert system, perhaps rule-based, that simulates the considerations of an ophthalmologist when presented with similar cumulative lesion information" (Paragraph 231), and "In somewhat more detail, the following lists DR lesions that are preferably detected and identified by all RGA algorithms. Sophisticated RGA algorithms for DR detect additionally the advantageous lesions. DR Lesions and Characteristics Preferably Identified…Fovea (or approximate foveal location)… Epi-retinal (or epi-papillary) neovascularization--size and distance to optic nerve head or fovea" (Paragraphs 252-265). The examiner further notes that paragraph 11 of the specification of the instant application defines a structural analysis of as "classification and quantification of structures at the ocular fundus (e.g., papilla, fovea)". The examiner further notes that **Sinclair** teaches **"a comparison unit connected to the image storage"** as "identify, and characterize in the prior retinal images lesions from the pre-determined set lesions type, comparing the lesions detected in the image taken at the selected time with the lesions detected in the prior image to detect changes in the lesions, and performing a decision process that assigns a grade to the retinal image taken at the selected time in dependence on the identities and characteristics of the lesions detected in that image, and in dependence on the changes in the lesions

detected in the comparing step" (Paragraph 44) and "Also, in preferred embodiments where prior retinal images are available and may be compared to a current retinal image, the time progression or regression of lesions may be identified. Then, detailed lesion information and lesion history may be taken into account in adjusting retinal image grading. For example, if a current image received a grade of level 2, but it contained lesions in critical anatomic regions as near the optic nerve head, or the fovea, or so forth, or contained rapidly growing or multiplying lesions, it may be promoted to grade level 3. Conversely, if a current image received a grade of level 3, but it contained regressing lesions in locations posing no threat of imminent visual impairment, it may be demoted to grade level 2 (or 2+) (Generally, grade level 3 signifies specialist consultation is recommended, while grade level 2 signifies that routine follow-up screening is recommended.)" (Paragraph 72). The examiner further notes that **Sinclair** teaches **"wherein the comparison unit can compare images to at least one image from a database of images"** as "identify, and characterize in the prior retinal images lesions from the pre-determined set lesions type, comparing the lesions detected in the image taken at the selected time with the lesions detected in the prior image to detect changes in the lesions, and performing a decision process that assigns a grade to the retinal image taken at the selected time in dependence on the identities and characteristics of the lesions detected in that image, and in dependence on the changes in the lesions detected in the comparing step" (Paragraph 44) and "The central database ("CDB") is an on-line (or otherwise efficiently accessible) storage repository of the data generated in an OSS system. The CDB stores patient oriented data such as original image data from patient screening examinations, results of RGA screening including images annotated or marked-up with lesion identification, associated patient identification, demographics, and screening/examination history, results of manual ophthalmologist grading process including any annotated images, referrals and reports. This database also stores system oriented data such as statistical data gathered from analysis of the patient data, results of the image quality assessment process, the `rules` to be used by the WFM for handling images, reports, and messages" (Paragraph 119), "Screening session identification (screening site identification, date, time, confirmation

of patient data, race (affects image processing parameters), sex, photographer, camera utilized and type of images acquired)", (Paragraph 131). The examiner further notes that **Sinclair** teaches **"the database of images comprising images of the same eye"** as "identify, and characterize in the prior retinal images lesions from the pre-determined set lesions type, comparing the lesions detected in the image taken at the selected time with the lesions detected in the prior image to detect changes in the lesions, and performing a decision process that assigns a grade to the retinal image taken at the selected time in dependence on the identities and characteristics of the lesions detected in that image, and in dependence on the changes in the lesions detected in the comparing step" (Paragraph 44) and "The central database ("CDB") is an on-line (or otherwise efficiently accessible) storage repository of the data generated in an OSS system. The CDB stores patient oriented data such as original image data from patient screening examinations, results of RGA screening including images annotated or marked-up with lesion identification, associated patient identification, demographics, and screening/examination history, results of manual ophthalmologist grading process including any annotated images, referrals and reports. This database also stores system oriented data such as statistical data gathered from analysis of the patient data, results of the image quality assessment process, the `rules` to be used by the WFM for handling images, reports, and messages" (Paragraph 119), "Screening session identification (screening site identification, date, time, confirmation of patient data, race (affects image processing parameters), sex, photographer, camera utilized and type of images acquired)", (Paragraph 131). The examiner further notes that **Sinclair** teaches **"wherein the contextual information is drawn from the settings of the fundus camera, manual annotations associated with the recorded fundus images, patient-specific information, and image contents"** as "The central database ("CDB") is an on-line (or otherwise efficiently accessible) storage repository of the data generated in an OSS system. The CDB stores patient oriented data such as original image data from patient screening examinations, results of RGA screening including images annotated or marked-up with lesion identification, associated patient identification, demographics, and screening/examination history, results of manual

ophthalmologist grading process including any annotated images, referrals and reports. This database also stores system oriented data such as statistical data gathered from analysis of the patient data, results of the image quality assessment process, the `rules` to be used by the WFM for handling images, reports, and messages" (Paragraph 119), "Screening session identification (screening site identification, date, time, confirmation of patient data, race (affects image processing parameters), sex, photographer, camera utilized and type of images acquired)", (Paragraph 131), "Screening session identification (screening site identification, date, time, confirmation of patient data, race (affects image processing parameters), sex, photographer, camera utilized and type of images acquired)" (Paragraph 134), "Equipment available (cameras, other resources)" (Paragraph 140), "RGA results from complete evaluation of all fundus images are stored in the Central Database. Preferably, RGA results include evaluated image annotated or marked-up with indicia to identify, e.g., the position or the identity of detected lesions. In cases of doubt, the annotation may include indications of "definitely a lesion," or "possibly a lesion." Annotations can include highlighting, coloring, outlining, pointing with arrows or the equivalent, and other methods known in the art (such as text superimposed on the image). Color coding of lesion characteristics may be used to simplify interpreting the annotations. The annotated images are saved (using an appropriate naming convention) along with the original images in the CDB" (Paragraph 228), and "Finally, RGAs have been discovered to be dependent on camera properties, digital image pixel density, depth and the magnification, and so forth. This dependence is preferably factored into RGA processing, for example, by inverse transforming known effects from the image" (Paragraph 238). The examiner further notes that **Sinclair** teaches **"wherein the comparison unit compares images recording in the image storage and creates new images of a similar pathology"** as "identify, and characterize in the prior retinal images lesions from the pre-determined set lesions type, comparing the lesions detected in the image taken at the selected time with the lesions detected in the prior image to detect changes in the lesions, and performing a decision process that assigns a grade to the retinal image taken at the selected time in dependence on the identities and characteristics of the lesions detected in that image,

and in dependence on the changes in the lesions detected in the comparing step" (Paragraph 44) and "Also, in preferred embodiments where prior retinal images are available and may be compared to a current retinal image, the time progression or regression of lesions may be identified. Then, detailed lesion information and lesion history may be taken into account in adjusting retinal image grading. For example, if a current image received a grade of level 2, but it contained lesions in critical anatomic regions as near the optic nerve head, or the fovea, or so forth, or contained rapidly growing or multiplying lesions, it may be promoted to grade level 3. Conversely, if a current image received a grade of level 3, but it contained regressing lesions in locations posing no threat of imminent visual impairment, it may be demoted to grade level 2 (or 2+) (Generally, grade level 3 signifies specialist consultation is recommended, while grade level 2 signifies that routine follow-up screening is recommended.)" (Paragraph 72).

Sinclair does not explicitly teach:

F) the database of images comprising images of other eyes.

Huang, however, teaches **"the database of images comprising images of other eyes"** as "Examples of such databases and apparatus are databases stored on disk storage that are accessible from a computer such as, for example, a personal computer. Still further, in accordance with these other embodiments of the present invention, the measures are compared with measures taken from normal eyes to diagnose eye disease, and the measures may also be compared with measures taken from the same patients (made over a period of time)" (Column 5, lines 66-67-Column 6, lines 1-6).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the cited references because teaching **Huang's** would have allowed **Sinclair's** to provide a method to enhance the monitoring of eye diseas, as noted by **Huang** (Column 6, lines 6-7).

Regarding claim 12, **Sinclair** further teaches a system comprising:

A) a means for determining deviations from a stored comparison image and/or from a standard image created by evaluating a plurality of comparison images, and/or a means for carrying out a similarity analysis by a stored comparison image and/or by a standard image created by evaluating a plurality of comparison images (Paragraphs 19, 166-167, 231-232, 234, and 252-267).

The examiner notes that **Sinclair** teaches **"a means for determining deviations from a stored comparison image and/or from a standard image created by evaluating a plurality of comparison images, and/or a means for carrying out a similarity analysis by a stored comparison image and/or by a standard image created by evaluating a plurality of comparison images"** as "Another significant element of this invention is one or more retinal grading algorithms that automatically evaluate the digital retinal images obtained by the screening subsystems for particular retinopathies. Generally, the RGAs operate in a lesion-based fashion, first identifying ophthalmologically significant retinal lesions or features by use of image processing methods, and second evaluating and grading the retinopathy in view of the identified lesions by use of artificial intelligence/cognitive decision capabilities" (Paragraph 19), "The RGAs are based on detecting and identifying "lesions" in fundus images. Therefore, each image (field of view) is evaluated to detect the number and type of lesions, and the cumulative lesion information for all acquired images is processed to arrive at a final retinopathy grade level for each eye. This processing may be by an expert system, perhaps rule-based, that simulates the considerations of an ophthalmologist when presented with similar cumulative lesion information" (Paragraph 231), and "In somewhat more detail, the following lists DR lesions that are preferably detected and identified by all RGA algorithms. Sophisticated RGA algorithms for DR detect additionally the advantageous lesions. DR Lesions and Characteristics Preferably Identified…Fovea (or approximate foveal location)… Epi-retinal (or epi-papillary) neovascularization--size and distance to optic nerve head or fovea" (Paragraphs 252-265).

Response to Arguments

6. Applicant's arguments filed 06/24/2009 have been fully considered but they are not persuasive.

Applicants argue on page 03 that **"However, Sinclair never discloses that any of the information in the CDB which might constitute contextual information, according to Claim 7, is used for either "determining deviations…" or "carrying out a similarity analysis…", as required by Claim 7. Rather, Sinclair only teaches that certain information can be stored in the CDB, and not that this information is used for either "determining deviations…" or "carrying out a similarity analysis…"**. However, the examiner wishes to state that the RGA analysis used by **Sinclair** is used to teach the claimed determining deviations and similarity analysis. Specifically, the defined contextual information which includes annotations (See Paragraph 228 of **Sinclair**), camera settings (See Paragraph 238 of **Sinclair**), image contents (See Paragraph 228 of **Sinclair**), and patient information (See Paragraph 119 of **Sinclair**), is all used by the RGA analysis for determining lesions. Thus, in contrast to applicant's contentions, **Sinclair's** RGA method clearly teaches using the contextual information for fundus analysis.

Applicants argue on page 04 that **"In Sinclair the determination and discrepancies between the images recorded by a fundus camera and a stored comparison image is carried out not on the basis of the contextual information but on the basis of the image content, particularly the actual disease. Otherwise, monitoring the course of the disease as intended by Sinclair would not be possible at all"**. However, the independent claims themselves define the contextual information to include "image contents". Thus, by applicant's own admission, **Sinclair** teaches that determination of potential hazards uses contextual information.

Applicants argues on page 04 that **"none of the portions of Sinclair to which Examiner cites disclosing...the process described for automatically grading the severity of the disease (RGA) must be carried out not on the basis of contextual information but based on the specific image contents"**. However, the independent claims themselves define the contextual information to include "image contents". Thus, by applicant's own admission, **Sinclair** teaches that determination of potential hazards

uses contextual information. Moreover, the defined contextual information which includes annotations (See Paragraph 228 of **Sinclair**), camera settings (See Paragraph 238 of **Sinclair**), image contents (See Paragraph 228 of **Sinclair**), and patient information (See Paragraph 119 of **Sinclair**), is all used by the RGA analysis for determining lesions. Thus, in contrast to applicant's contentions, **Sinclair's** RGA method clearly teaches using the contextual information for fundus analysis.

Applicant argues on page 04 that **"The Examiner further asserts that Sinclair describes "a similarity analysis of the contextual information of a stored comparison image and/or of a standard image,…with similar pathology." We also dispute this. On the contrary, the specification, particularly [072] and [0166], shows that the database is searched for images of the same patient for a comparison in order to prepare a disease history [0072]. Contextual information is not required for this, nor would it be useful"**. However, the examiner wishes to state that because the independent claims have an "and/or" operator, limitation "b" does not need to be taught if limitation "a" is taught, as the above office action displays.

Applicant argues on page 05 that **"Applicant continues to maintain that Sinclair does not disclose that contextual information is drawn from the "Settings of the fundus camera", as required by Claim 7…these are camera properties, and not camera settings (e.g., recording mode, field angle, exposure settings). Settings and properties of cameras are two completely different things, as properties are fixed whereas settings can be set (i.e., changed). Thus, while Sinclair may disclose that RGAs have been discovered to be dependent upon camera properties, Sinclair completely fails to disclose that settings of the fundus camera are used as contextual information…Claim 7"**. However, the examiner wishes to state that there is no definition nor explanation of what the claimed settings constitute. Thus, the claimed camera settings are unequivocally broad and the camera properties of **Sinclair** teach the aforementioned. In addition, the camera properties of **Sinclair** nevertheless teach the claimed camera settings. Specifically, the examiner wishes to refer to Paragraph 238 of **Sinclair** which states "Finally, RGAs have been discovered to be dependent on camera properties, digital image pixel density, depth

and the magnification, and so forth. This dependence is preferably factored into RGA processing, for example, by inverse transforming known effects from the image" (Paragraph 238). The examiner further wishes to state that magnification is clearly an adjustable feature of camera. Moreover, In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "**recording mode, field angle, exposure settings**") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent 6,757,409 issued to **Marshall et al.** on 29 June 2004. The subject matter disclosed therein is pertinent to that of claims 7-12 (e.g., methods to capture, store, analyze, compare, and retrieve fundus images).

U.S. PGPUB 2004/0156016 issued to **Kerr et al.** on 12 August 2004. The subject matter disclosed therein is pertinent to that of claims 7-12 (e.g., methods to capture, store, analyze, compare, and retrieve fundus images).

U.S. Patent 7,055,955 issued to **Kishida et al.** on 06 June 2006. The subject matter disclosed therein is pertinent to that of claims 7-12 (e.g., methods to capture, store, analyze, compare, and retrieve fundus images).

U.S. Patent 6,755,526 issued to **Shibata** on 29 June 2004. The subject matter disclosed therein is pertinent to that of claims 7-12 (e.g., methods to capture, store, analyze, compare, and retrieve fundus images).

U.S. Patent 6,112,114 issued to **Dreher** on 29 August 2000. The subject matter disclosed therein is pertinent to that of claims 7-12 (e.g., methods to capture, store, analyze, compare, and retrieve fundus images).

U.S. Patent 6,409,342 issued to **Ohnyuma et al.** on 25 June 2002. The subject matter disclosed therein is pertinent to that of claims 7-12 (e.g., methods to capture, store, analyze, compare, and retrieve fundus images).

U.S. Patent 6,928,193 issued to **Gersten** on 09 August 2005. The subject matter disclosed therein is pertinent to that of claims 7-12 (e.g., methods to capture, store, analyze, compare, and retrieve fundus images).

U.S. Patent 5,287,129 issued to **Sano et al.** on 15 February 1994. The subject matter disclosed therein is pertinent to that of claims 7-12 (e.g., methods to capture, store, analyze, compare, and retrieve fundus images).

U.S. Patent 6,053,865 issued to **Sugiyama et al.** on 25 April 2000. The subject matter disclosed therein is pertinent to that of claims 7-12 (e.g., methods to capture, store, analyze, compare, and retrieve fundus images).

U.S. Patent 5,993,001 issued to **Bursell et al.** on 13 November 1999. The subject matter disclosed therein is pertinent to that of claims 7-12 (e.g., methods to capture, store, analyze, compare, and retrieve fundus images).

U.S. Patent 5,557,9471 issued to **Barber et al.** on 26 November 1996. The subject matter disclosed therein is pertinent to that of claims 7-12 (e.g., methods to capture, store, analyze, compare, and retrieve fundus images).

U.S. Patent 6,766,041 issued to **Golden et al.** on 20 July 2004. The subject matter disclosed therein is pertinent to that of claims 7-12 (e.g., methods to capture, store, analyze, compare, and retrieve fundus images).

U.S. Patent 6,453,057 issued to **Marshall et al.** on 17 September 2002. The subject matter disclosed therein is pertinent to that of claims 7-12 (e.g., methods to capture, store, analyze, compare, and retrieve fundus images).

U.S. Patent 6,714,672 issued to **Berestov et al.** on 30 March 2004. The subject matter disclosed therein is pertinent to that of claims 7-12 (e.g., methods to capture, store, analyze, compare, and retrieve fundus images).

U.S. Patent 6,,179,421 issued to **Pang** on 30 January 2001. The subject matter disclosed therein is pertinent to that of claims 7-12 (e.g., methods to capture, store, analyze, compare, and retrieve fundus images).

U.S. Patent 6,840,933 issued to **Pang et al.** on 11 January 2005. The subject matter disclosed therein is pertinent to that of claims 7-12 (e.g., methods to capture, store, analyze, compare, and retrieve fundus images).

U.S. Patent 7,025,459 issued to **Cronsweet et al.** on 11 April 2006. The subject matter disclosed therein is pertinent to that of claims 7-12 (e.g., methods to capture, store, analyze, compare, and retrieve fundus images).

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mahesh Dwivedi whose telephone number is (571) 272-2731. The examiner can normally be reached on Monday to Friday 8:20 am – 4:40 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tim Vo can be reached (571) 272-3642. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mahesh Dwivedi
Patent Examiner

Art Unit 2168

September 25, 2009

/Mahesh H Dwivedi/

Examiner, Art Unit 2168

/Tim T. Vo/

Supervisory Patent Examiner, Art Unit 2168